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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,796	10/01/2001	David M. Goldenberg	018733-1060	3640

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,796	GOLDENBERG, DAVID M.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/25 & 08/31/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-27,36-44,47,52 and 55-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27,36-44,47,52 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 26, 2006 has been entered.

2. Claims 24-27, 36-44, 47, 52 and 55-59 are pending.

Claims 45, 60-89 and 91-97 have been cancelled.

Claims 24, 36-44 and 52 have been amended.

Claims 24-27, 36-44, 47, 52 and 55-59 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 60-70, 73-79 and 91-93 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,789,554 (filed July 31, 1996) is withdrawn in light of the cancellation of the listed claims.

4. The rejection of claims 60-70, 73-77, 79 and 91-93 under 35 U.S.C. 102(b) as being anticipated by WO 96/04925 (22 February 1996/ IDS reference A8) is withdrawn in light of the cancellation of the listed claims.

5. The rejection of claims 60-65, 67-69 and 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Juweid et al. (Cancer Research (Suppl.) 55:5899s-5907s, December 1, 1995/ IDS reference A20) is withdrawn in light of the cancellation of the listed claims.

Claim Rejections - 35 USC § 103

6. The rejection of claims 60-89 and 91-97 under 35 U.S.C. 103(a) as being unpatentable over Juweid et al. (Cancer Research (Suppl.) 55:5899s-5907s, December 1, 1995/ IDS reference A20) and U.S. Patent number 5,698,178 (filed April 8, 1998) is withdrawn in light of the cancellation of the listed claims.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 103

7. The rejection of claims 24-26, 36-38, 44, 47, 52 and 55-57 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and in further view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and Li et al. (Cellular Immunology 118: 85-99, 1989) is maintained. Claims 45, 60-70, 73-79 and 91-93 have been cancelled.

Applicant argues "'[c]onventional therapies' at the time of the Maloney article, circa 1994, were chemotherapies, not antibody therapies" and consequently "the disclosure in Maloney that anti-CD20 may be combined with a 'conventional therapy' would not have suggested a combination with anti-CD22 immunoconjugate therapy"., see page 6 of Remarks submitted July 25, 2006.

Applicant asserts, "Maloney teaches away from any use of immunoconjugates, and thus improperly combined with [the patent]....", see bridging paragraph of pages 6 and 7 of the Remarks. Applicant points out a passage from Maloney on page 2585, however the Maloney reference consists of pages 2457-2466. Applicant also notes "...***anti-CD22*** antibody labeled with a drug or a radioisotope other than I131.", see bridging paragraph of pages 7 and 8.

Applicant provides a definition of "conventional" and avers investigational drugs in Phase I clinical trials are not considered conventional therapy, see 1st full paragraph on page 8 of Remarks. Applicant provides reviews and texts allegedly supporting the fact that combination antibody therapy is not conventional. Applicant concludes arguments with "Maloney's mention in 1994 of a combination of anti-CD20 antibody with 'conventional therapies' would encompass combination antibody therapy as presently claimed.", see 3rd paragraph of page 11. These points of view, articles and arguments have been carefully considered, but found unpersuasive.

In the instant case, the Examiner regards the CD22 as a conventional therapy. Any reference to the CD20 as conventional therapy in previous Actions was in error. Maloney noted "using antibody [CD20] alone or in combination with conventional

therapies, may provide the greatest benefit.", see page 2465, column 1, last paragraph. Webster's Collegiate dictionary defines conventional as developed, established, or approved by general usage; customary, see accompanying reference. The definition also includes conforming to established practice or accepted standards. Patent '554 sets forth the "[c]onjugates of chimeric and humanized chimeric LL2 antibodies with cytotoxic agents or labels... use[d] in therapy...of B-cell lymphomas and leukemias", see last sentence of the Abstract and column 2, lines 56-62 of U.S. patent #5,789,554. It is clear from the patent and specific quote from said patent this therapy has been developed and established and is reasonably regarded as a conventional therapy as supported by the definition of "conventional". The face of the patent also notes references directed CD22 directed therapies as early as April 1991. The practice of administering CD22 has been established since 1991.

Moreover, Applicant's assertion of 'conventional therapies' seems to be based on opinion and not scientific evidence. Applicant also notes "...***anti-CD22*** antibody labeled with a drug or a radioisotope other than I131.", and the claims no longer contain this limitation. In the literature provided by Applicant there is no scientific evidence presented teaching one of ordinary skill in the art away from combining the prior art references to arrive at the claimed invention at the time of filing. Applicant asserts statements in articles contravene the Examiner's position, however the evidence provided does not preclude the therapeutic use of CD22, a known, established practice as a conventional therapy.

Therefore, the rejection of record is maintained.

8. The rejection of claims 24-27, 36-38, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,106,955 (April 21, 1992) is maintained. Claims 45, 60-70, 73-77 and 91-93 have been cancelled.

Applicant's arguments are the same as presented above. For the reasons of record the rejection is maintained.

9. The rejection of claims 24-26, 36-42, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11), U.S. Patent Number 5,686,072 (filed February 22, 1994/ IDS reference A1) and WO 95/09917 (April 13, 1995/ IDS reference A5) is maintained. Claims 45, 60-70, 73-77 and 91-93 have been cancelled.

Applicant's arguments are the same as presented above. For the reasons of record the rejection is maintained.

10. The rejection of claims 24-26, 36-39, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and European Patent Application 0 510 949 A2 (October 28, 1992/

IDS reference A4) is maintained. Claims 45, 60-70, 73-77 and 91-93 have been cancelled.

Applicant's arguments are the same as presented in the initial 103 rejection. For the reasons of record the rejection is maintained.

11. The rejection of claims 24-27, 36-38, 43, 44, 52 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998) is maintained. Claims 45, 60-89 and 91-97 have been cancelled.

Applicant's arguments are the same as presented in the initial 103 rejection. For the reasons of record the rejection is maintained.

12. The rejection of claims 24-27, 38, 43, 44, 52 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over WO 96/04925 (22 February 1996/ IDS reference A8), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998) is maintained. Claims 45, 60-89 and 91-97 have been cancelled.

Applicant's arguments are the same as presented in the initial 103 rejection. For the reasons of record the rejection is maintained.

Double Patenting

13. The provisional rejection of claims 24-27, 36-44, 47, 52 and 55-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-44 of copending Application No. 10/314,330 (filed December 9, 2002) is maintained. Claims 45, 60-89 and 91-97 have been cancelled.

Applicant requests for the instant rejection to be held in abeyance until indication of allowable subject matter has been indicated at which time they would consider filing a terminal disclaimer.

The request has been considered, but found unpersuasive. At this point in prosecution the rejection is maintained for the reasons of record in listed in the first action on the merits (FAOM) mailed April 4, 2005.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
06 November 2006
ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER